EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY VIRGINIA MASON MEDICAL CENTER PROPOSING TO ESTABLISH A FREE-STANDING AMBULATORY SURGERY CENTER IN FEDERAL WAY

PROJECT DESCRIPTION

Virginia Mason Medical Center (VMMC) is a private, not-for-profit provider of health care services in Seattle. The hospital's website describes the Virginia Mason organization as follows:

- "A Staff of nearly 5,000, including a multi-specialty group practice of 480 physicians;
- An acute-care teaching hospital licensed for 336 beds;
- A network of clinics throughout the region including a sports medicine facility;
- Benaroya Research Institute at Virginia Mason;
- Bailey-Boushay House, a nursing residence and day health center for people living with HIV, AIDS, and other complex nursing needs;
- Virginia Mason Foundation, supporting important advances in clinical care and research at Virginia Mason."

[source: Virginia Mason web site at http://www.virginiamason.org]

Among the various facilities operated by VMMC are nine community clinics and five ambulatory surgery centers. Each of these facilities' use is limited to employees of VMMC

This project under review is related to the ambulatory surgery center located at Virginia Mason Federal Way. Virginia Mason Federal Way ASC has been in continuous operation since 1999. The current legal structure of the facility qualified it for an exemption from Certificate of Need review as an ASC under Washington Administrative Code (WAC) 246-310-010. [source: CN historical files] Virginia Mason Federal Way has 4 operating rooms (ORs) and offers pain management, gastroenterology, general surgery, gynecology, orthopedic surgery, otolaryngology, plastic surgery and urology procedures. [source: Application, p8]

This project proposes to open surgical privileges at Federal Way to physicians not employed by VMMC. This action results in the facility becoming a freestanding ASC as defined in WAC 246-310-010. Virginia Mason does not anticipate a change in the number of ORs at the facility or the types of procedures offered.

Given that the ASC was established in 1999 the department did not require Virginia Mason to identify the capital costs for its establishment at that time. Therefore, there is no capital cost associated with this project.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

APPLICATION CHRONOLOGY

May 16, 2005	Letter of Intent Submitted			
November 15, 2005	Application Submitted			
November 15, 2005	Department's Pre-Review Activities			
through April 21, 2006	 1st screening activities and responses 			
	 2nd screening activities and responses 			
May 8, 2006	Department Begins Review of the Application			
	 public comments accepted throughout review 			
June 12, 2006	Public Hearing Conducted in Federal Way			
	 End of Public Comment 			
August 14, 2006	Department's Anticipated Decision Date			
October 17, 2006	Department's Actual Decision Date			

AFFECTED PARTIES

Throughout the review of this project, four other entities sought and received interested person status under WAC 246-310-010:

- Auburn Regional Medical Center, an acute care hospital located in Auburn
- Enumclaw Regional Hospital, an acute care hospital located in Enumclaw
- St. Francis Community Hospital, an acute care hospital located in Federal Way
- Valley Medical Center, an acute care hospital located in Renton

SOURCE INFORMATION REVIEWED

- Virginia Mason Medical Center's Certificate of Need Application dated November 15, 2005
- Virginia Mason Medical Center's supplemental information dated February 24, 2006, and April 21, 2006
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2002, 2003, and 2004 summaries)
- Population data obtained from the Office Financial Management based on year 2000 census published January 2002.
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Data obtained from Virginia Mason Medical Center's website
- Quality of Care surveys for Washington and out-of state health care facilities owned, operated, or managed by Virginia Mason Medical Center.
- Certificate of Need Historical files

CRITERIA EVALUATION

To obtain Certificate of Need approval, the applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment) and WAC 246-310-270 (ambulatory surgery).

CONCLUSION

For the reasons stated in this evaluation, Virginia Mason Medical Center's proposal to establish an ambulatory surgery center in Federal Way is not consistent with the applicable criteria and a certificate of need should be denied.

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6) and WAC 246-310-240(2) and (3).

A. Need (WAC 246-310-210)

Based on the source information reviewed the department determines that the application is not consistent with the applicable need criteria in WAC 246-310-210.

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need Virginia Mason currently operates the four-OR Federal Way ASC as an exempt facility, open only to members or employees of its group practice. If awarded a certificate of need, VMMC intends to allow non-VMMC physicians to serve patients insured by Group Health Cooperative and Pacific Medical Center in addition to its current volume.

The applicant is projecting, based on historical utilization, an annual increase in surgical and pain management procedures of 5% in the 2007 and 2008, followed by a more modest growth of approximately 1%. VMMC Federal Way's historical and projected volumes are outlined in Table 1, below:

Table I Virginia Mason Federal Way Utilization (Actual and Projected)

Year	Surgical Procedures	Pain Management	Total Procedures
		Procedures	
2002*	3,797	280	4,077
2003*	3,624	367	3,991
2004*	3,484	337	3,821
2005**	3,352	402	3,754
2006**	3,435	412	3,847
2007**	3,608	433	4,041
2008**	3,788	454	4,242

^{*}Actual Volumes

[source: Application, pp6 and 8]

The Department of Health's Certificate of Need Program uses the methodology found in WAC 246-310-270 for determining the need for additional freestanding ASCs in Washington State. The methodology provides a basis of comparison of existing operating room (OR) capacity for both outpatient and inpatient OR's in planning areas using the current utilization of existing providers. The numeric portion of the methodology requires a calculation of annual capacity of existing ORs, both outpatient and inpatient, and excludes specialized dedicated rooms. Examples of 'dedicated' rooms are open heart surgery rooms, delivery rooms, cystoscopic rooms, and endoscopic rooms.

The methodology separates the state into several planning areas, described variously as individual counties, groups of counties, or sub-areas of counties. The applicant is proposing to establish an ASC in Federal Way, which is located in the area described in the methodology as Southeast King.

The Southeast King planning area contains nineteen providers of surgical services: four hospitals and fifteen ASCs. These providers are listed on the following page:

^{**}Projected Volumes

Hospital/City

Auburn Regional Medical Center, Auburn Enumclaw Regional Hospital, Enumclaw St. Francis Community Hospital, Federal Way Valley Medical Center, Renton

ASC/City

Auburn Outpatient Surgery Center, Auburn Cascade Surgery Center, Auburn Digestive Health Network Endoscopy Center, Federal Way Evergreen Eye Surgery Center, Federal Way Lomas Eye Care Center, Renton

ASC/City

MultiCare Covington Day Surgery Center, Kent Plastic and Reconstructive Surgeon, Renton Puget Sound Plastic Surgery, Federal Way Rainier Surgical Center, Federal Way Surgery Center of Enumclaw, Enumclaw Valley Endoscopy Center, Renton Valley Eye and Laser Surgery Center, Renton Valley Orthopedic Associates ASC, Renton

Valley Podiatric ASC, Renton Virginia Mason Federal Way ASC

Of the nineteen providers, eighteen² were asked to provide the department with information about their OR capacity, surgical volumes, and types of surgeries performed. Of the eighteen providers surveyed, only three returned completed information requests: Enumclaw Regional Hospital, Digestive Health Network Endoscopy Center, and Rainier Surgical Center. The remaining three hospitals provided some similar information in the documents they provided in opposition to this project. Each of the four hospitals provides both inpatient and outpatient surgery. Of the fifteen ASCs in the planning area, only three³ are CN-approved and open for use by physicians outside the owners' group practices. One of those three providers, Digestive Health Endoscopy Network Surgery Center, provides services only in dedicated special procedure rooms and does not have any ORs for general outpatient surgical use. The remaining twelve ASCs are CN-exempt facilities whose use is limited to members or employees of the practices where they are located. As a result, only the ORs at the four hospitals and Auburn Outpatient Surgery Center and MultiCare Covington Surgery Center are considered in the department's capacity calculations.

During the course of the review, the applicant provided several interpretations of the methodology contained in WAC 246-310-270. In its initial application, VMMC provided an interpretation of the methodology based on the department's 2002 remanded decision awarding a certificate of need to Auburn Outpatient Surgery Center. In that evaluation, the department calculated a surgical use rate of 78.20 surgeries per thousand residents in the Southeast King planning area. VMMC revised the use rate downward in response to volume data for the four hospitals. Surgical volumes for the other providers in the area were estimated from data contained in earlier CN evaluations and also from the hospital data submitted to the department. VMMC also provided estimated populations for the area in 2005 and 2007. VMMC's population and surgical volume estimates created a use rate of 77.52 surgeries per thousand residents. Using the applicant's estimated volume and population values as presented in the application, the department's methodology would project a need for 13 additional outpatient ORs in the planning area.

At the public hearing, VMMC provided a second set of calculations, incorporating different population and volume figures, resulting in a higher use rate, 84.19 surgeries per 1,000 residents. Inserting those values into the department's methodology, a need for as many as 19 additional outpatient ORs is indicated in the planning area.

² The applicant, an existing exempt ASC, was not surveyed because the application contains this information.

³ Auburn Outpatient Surgery Center, MultiCare Covington Day Surgery Center, Digestive Health Network Endoscopy Center.

During the public comment and rebuttal phases of the review, the four area hospitals provided written critiques of VMMC's methodologies. In those discussions, the hospitals disagreed with the population projections, historical surgical volumes at the area hospitals, and use rate calculations proposed by VMMC. Using the assumptions employed by the affected parties, including a use rate of 63.3 surgeries per thousand residents, the department's methodology would indicate that the Southeast King planning area currently has a surplus of approximately 3.42 mixed-use ORs. Adjusting the affected parties' 2005 population estimate by their assumed growth rate of 1.5% returns a surplus in 2009 that is smaller than the 2005 estimate, but still shows a surplus of 1.58 mixed-use ORs.

In its rebuttal submission, VMMC presented a third set of need projections, based on the population projections from its initial application, the surgical volumes reported by the affected parties at the public hearing, the count of operating rooms reported by the affected parties at the public hearing, and an estimated use rate of 102 surgeries per 1,000 residents. This presentation of the methodology returns an estimated need for 22 additional outpatient ORs in 2009.

VMMC contended that the use rate presented in the rebuttal submission is appropriate to this planning area because 1) the department has accepted this use rate in a recent evaluation in the East King planning area (adjacent to the Southeast King planning area discussed in this evaluation), and 2) the consultant retained by the affected parties in this case is the same consultant who authored the arguments in favor of the 102 surgeries/1,000 residents use rate in that recent case. In that recent case, the simultaneous review of applications from Swedish Health Services and Proliance Surgeons, each proposing to establish ASCs in Issaquah, in the East King planning area, the department received survey responses from 9 of 28 providers of surgical services. The department had historical data for seven additional providers, resulting in 16 of 28 providers for which data was available to determine a use rate. In that case, the department concluded that it had insufficient data and relied upon studies presented by both applicants that demonstrated that higher use rates, such as the 102/1,000, might be more appropriate.

In the current case, the department has received survey responses or other acceptable data from 7 of 19 providers. The applicant, however, provided credible estimates of the volumes of the existing providers in its initial application. Those estimates were accepted (with minor adjustments) by the affected parties and used in their comment and rebuttal. It is only with submission of VMMC's rebuttal comments that it adopted the argument that the use rates calculated from its own estimates The department concludes that the applicant based its application on the estimated surgical volumes presented in the initial application and public hearing documents and cannot, at the rebuttal phase, adopt an entirely new rationale for the approval of this project unless that new rationale is in response to information or arguments raised during the comment phase of the review. The department concludes that VMMC's adoption of the 102/1,000 use rate is not in response to any information or arguments raised by any party in this case. The department further concludes that VMMC has provided no evidence that this use rate is more appropriate to the Southeast King planning area than its own proposed use rate, based on estimated volumes at area providers. The department concludes, therefore, that it would be inappropriate to adopt this use rate at this stage of the review, and instead based its evaluation of this project on the reported and estimated volumes of the various providers in Southeast King.

Using the 2005 and 2009 population estimates provided by VMMC, the actual surgical volume and capacity data provided by the four hospitals, VMMC, and the responding ASCs, the estimated surgical volume data prepared by VMMC during the review of this project, the department concludes that a surplus of 1.89 mixed-use ORs is to be expected in this planning area in 2009, at a use rate of 75.96 surgeries per thousand residents. This calculation is based on the current capacity of the hospitals and CN-approved ASCs in the planning area.

During the public comment phase of the application, Valley Medical Center indicated that it is currently engaged in construction projects that will add an additional 7 mixed-use ORs. The department reviewed documents on file with its Construction Review Services program and confirmed that plans currently under review by the department include additional ORs. As a consequence, the supply of OR's to be counted could include these rooms currently under construction and would serve to increase the projected surplus of ORs to 8.89.

According to the provisions of WAC 246-310-270(4), "Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need." In this case, existing ORs at two of the planning area hospitals are operating in excess of 85% of the capacity assumed by 246-310-270(9)(a) for mixed-use operating rooms, however the other two hospitals are utilized between only 38% and 58% of available capacity. The addition of seven additional ORs at Valley Medical center will decrease that facility's utilization dramatically. No factors have been identified by VMMC that would compel the department to approve additional capacity.

In its initial application, VMMC noted that, as a currently-operating exempt ASC, the facility's four ORs would not actually create any new capacity in the planning area. While no new ORs would be constructed as a result of approval of this project, the number of ORs the department counts in evaluating need would, in fact, increase. As has been noted above, there is a current and projected surplus of OR capacity in the planning area without counting VMMC's four ORs. Addition of those ORs will only exacerbate that projected surplus.

Based on the above information, the department concludes that this sub-criterion is not met.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

A facility's admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility, and any assurances regarding access. To demonstrate compliance with this sub-criterion, VMMC provided copies of the following policies and procedures instead of an admissions policy: Charity Care, Guidelines for Appropriate Cases for the Outpatient Surgery Center, Outpatient Surgery Eligibility for Pediatric Patients, and Patient Rights and Responsibilities. [source: Application, Exhibit 11; February 24, 2006 screening responses, Appendix 2; April 21, 2006, screening responses, Appendix 2] Of these policies, both the charity care and patient rights and responsibilities policies confirm that all residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons,

⁴ Using OR capacity definitions in WAC 246-310-270(9)(a), 2005 utilization of the four hospitals was: St. Francis Community Hospital, 96.49%; Valley Medical Center, 86.47%; Auburn Regional Medical Center, 58.22%; Enumclaw Regional Hospital, 37.95%.

and other underserved groups and the elderly are likely to have adequate access to the facilty or charitable care at the ASC. The department concludes that the documents discussed above provide the department with reasonable assurance that services at the ASC are and will be available to the underserved groups identified in WAC 2469-310-210(2).

The department uses a facility's Medicaid eligibility or contracting with Medicaid as the measure to determine whether low income residents would have access to the proposed services. VMMC is a participant in the Medicaid program. In addition, VMMC's current and projected sources of reimbursement include Medicaid. Based on this information and the other information included in the application and charity care policy, the department concludes that low income residents would have access to the proposed services.

Similarly, the department uses a facility's Medicare certification as the measure to determine whether elderly patients would have access to the proposed services. Based on the facility's history as a Medicare-certified provider and revenue projections including compensation from Medicare, the department concludes that elderly patients would have access to the proposed services.

The department concludes that there is reasonable assurance that the proposed services will be available and accessible to all residents for whom they are appropriate, contingent upon the submission of an adopted admissions policy consistent with the draft provided during the course of review.

WAC 246-310-270(7) states that ASCs shall implement policies to assure access to individuals unable to pay consistent with charity care levels reported by the hospitals affected by the proposed ASC. According to charity care data obtained from OHPDS, the 2002-2004 average for the facilities in the planning area⁵ is 1.19% of gross revenue and 1.96% of adjusted revenue. [source: OHPDS 2002-2004 charity care summaries]

To demonstrate compliance with this charity care criterion, VMMC submitted its charity care policy, however, the policy does not identify the percentage of charity care to be provided by the ASC. The applicant's pro formas indicate that the ASC will provide charity care at approximately .96% of total revenue and 1.66% of adjusted revenue, which is below the average charity care provided by the other hospitals in the planning area. [source: April 21, 2006, screening responses] Based on the percentages of charity care identified in the application, the department concludes that a condition related to the charity care to be provided at the ASC is necessary.

The department concludes that any approval of this project must be conditional upon the proposed ASC providing charity care at the planning-area levels outlined above. With this condition, this sub-criterion is met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant has not met the applicable financial feasibility criteria in WAC 246-310-220.

⁵ Auburn Regional Medical Center, Enumclaw Regional Hospital, St. Francis Community Hospital, Valley Medical Center

(1) The immediate and long-range capital and operating costs of the project can be met.

To analyze short- and long-term financial feasibility of hospital projects and to assess the financial impact of a project on overall facility operations, the department uses financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios utilized are 1) long-term debt to equity ratio; 2) current assets to current liabilities ratio; 3) assets financed by liabilities ratio; 4) total operating expense to total operating revenue ratio; and 5) debt service coverage ratio. If a project's ratios are within the expected value range, the project can be expected to be financially feasible.

Table II, below, shows the financial ratios that VMMC projects in the first three years of operation for the ASC and the Office of Hospital and Patient Data Systems (OHPDS) year 2005 financial ratio guidelines for hospital operations. [source: OHPDS analysis, p3]

Table II VMMC Federal Way ASC Projected Financial Ratios

Financial Ratio	OHPDS		VMMC	Year 1	Year 2	Year 3
	Guideline		2005			
Long Term Debt to	0.507	*Below	1.222	N/A	N/A	N/A
Equity						
Current Assets/Current	2.084	*Above	1.451	N/A	N/A	N/A
Liabilities						
Assets Financed by	0.419	*Below	0.641	N/A	N/A	N/A
Liabilities						
Operating Expense to	0.952	*Below	0.995	0.844	0.839	0.834
Operating Revenue						
Debt Service Coverage	4.944	*Above	3.325	N/A	N/A	N/A

^{* =} a project is considered more feasible if the ratios are above or below the value/guideline as indicated

After reviewing the financial information provided by VMMC, staff from OHPDS stated the following:

"Virginia Mason Medical Center (VMMC) is a "controlled affiliate" of Virginia Mason Health System (VMHS). DOH/HPDS does not have financial information for the Virginia Mason Health System as a whole.

"The financial status of VMMC is adequate to fund their participation in this project. This project will not adversely impact reserves, or total assets, total liability or the general health of Virginia Mason Medical Center.

"I have also reviewed various ratios' that can give a picture of the financial health of Virginia Mason ambulatory surgery center in Federal Way. I have also reviewed various ratios' that can give a picture of the financial health of VMMC. The applicant did not provide a Balance Sheet or Cash Flow statement for the ASC. These reports are not critical for this application. Important ratios used by Certificate of Need are listed below. The A means it is better if the hospital number is above the State number and B means it is better if the hospital number is below the state number. Virginia Mason ambulatory surgery center in Federal Way Income statement ratio is

above average at the end of the 3rd year and the ASC is better than break even as required by CON rules. VMMC ratios for 2005 are all below average compared to the state averages for 2005. While this is not a good situation, the ratios are still within appropriate range of the average especially given that VMMC will not have any capital expenditure for this project.

"The project Operating Expense/Operating Revenue ratio is appropriate. The applicant projects an above average financial foundation for the ASC. The applicant should not have any trouble meeting the immediate and long term needs of this project. This criterion is satisfied." [source: OHPDS analysis, p3]

Based on this information, the department concludes that the long-term capital and operating costs of this project can be met.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

Based on the projected number of cases shown in Table I, Table III below shows the projected revenues, expenses, and net income projected by the applicant for the first three years of operation:

Table III VMMC Federal Way Projected Revenue and Expenses

VMMC Federal Way Projected Revenue and Expenses					
	Year 1 (2007)	Year 2 (2008)	Year 3 (2009)		
Number of Procedures	4,041	4,242	4,454		
Net Patient Revenue*	4,199,645	4,409,627	4,630,109		
Total Expenses**	3,524,922	3,677,184	3,763,154		
Net Income	674,723	732,443	866,954		
Operating Revenue per Surgery	1039.26	1039.52	1039.54		
Operating Expense per Surgery	872.29	866.85	844.89		

166.97

172.66

194.65

Net Income per Surgery

OHPDS staff provided the following discussion of this sub-criterion:

"Virginia Mason ambulatory surgery center in Federal Way statistics for year three are appropriate.

"This office does not have much data on outpatient surgery costs. The data we have is reported under a cost center called Short Stay that covers ambulatory surgery but also can cover other treatments which result in stays less than 24 hours. The applicant's charges and expenses are similar to the actual 2005 short stay cost center data.

"The project costs to the patient and community are similar to current providers. This criterion is satisfied." [source: OHPDS evaluation, pp 2-3]

The department also examined the revenue and expense projections provided by VMMC in light of the department's finding that need for this project has not been demonstrated. Even though the

^{*}includes deductions for charity care

^{**}includes depreciation and interest expenses

department did not find need for additional OR capacity in the planning area, the existing VMMC facility has been in operation for several years. Volume assumptions in this project are based on modest growth projections. The department concludes it is possible that VMMC would have sufficient utilization to ensure the facility's profitability and not cause this facility to have an unreasonable impact on the costs and charges for health services. If, however, implementation of this project would cause under-utilization and/or inefficient operation of other facilities, this project might have an unreasonable impact on those costs and charges. For this reason, this criterion is not met.

(3) The project can be appropriately financed.

There is no capital cost associated with this project. In addition, the department's examination of the projected financial statements for this facility indicates that VMMC should be able to meet the operating costs of the ASC. This sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has not met the applicable structure and process (quality) of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

Given that the ASC is currently operating, the applicant proposes only minimal increases in staff if this project is approved. Table IV below shows the current and projected staffing of the ASC. [source: application, p21]

Table IV Virginia Mason Federal Way ASC Current and Projected Staffing

	Current	2006	2007	2008	Total
Staff	2005	Incremental	Incremental	Incremental	FTEs
Manager	.3	0	0	0	.3
Professional Staff	.4	0	0	0	.4
Supervisor	1	0	0	0	1
RN	7.1	0	.4	.4	7.9
RN IP Contract	0	0	0	0	0
LPN and OA	3.1	0	0	0	3.1
Technician	2	0	0	0	2
Technician OR	1.4	0	.4	.4	2.2
Total	15.3	0	.8	.8	16.9

As indicated in Table IV, above, the applicant is anticipating adding only 1.6 total FTEs in the first three years of the project. In order to demonstrate the availability of the additional staff time, VMMC provided the following discussion:

"Virginia Mason Federal Way ASC proposes to expand the working hours for its clinical staff to meet the incremental increase in volumes. Virginia Mason Federal Way's clinical staff currently have several part-time positions. Our staff has indicated that they are willing to expand their work hours. For this reason, we believe that there will be

sufficient numbers of qualified health care providers. Existing management personnel are sufficient to meet the incremental volume need." [source: application, p22]

The department concludes that the addition of only 1.6 FTEs to an ASC that is part of an entity employing nearly 5,000 people is reasonable and achievable, particularly when that addition is achieved chiefly by expanding the schedules of currently part-time employees. The department concludes that this sub-criterion is met.

(2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

To demonstrate compliance with this sub-criterion, VMMC provided only an Executed Transfer Agreement with St. Francis Community Hospital. [Application, Appendix 15] When questioned about the lack of documentation of the availability of ancillary and support services for this project, VMMC provided the following reply:

"Our ancillary support services on site include radiology, lab, and cardiology. They exist as part of the attached outpatient clinic and are fully staffed from 8 AM to 7 PM without regard to our ASC census. By the nature of outpatient surgery, we rarely use any of these, but they are open throughout the time we have patients on site and available to us during the entire day. We employ x-ray approximately 1-2 times per month for post-op films and 8-10 times per month for breast mass location procedures. We order approximately 1-2 EKGs per month, and once per month we check a pregnancy test via the lab. Thus, the incremental increase in surgery cases will result in only marginal increase in the use of ancillary and support services. Because of the low utilization of ancillary services, the existing services will be more than adequate for any increase in surgery cases." [source: February 24, 2006, screening responses, p3]

The department concludes that, since this application proposes an increase in OR utilization of only approximately 11% over 2005 values by allowing non-VMMC physicians to use the ASC, and that no new specialty services or significant changes in healthcare delivery are expected to result from this project, VMMC's assertions that current support services are sufficient to support the project are reasonable.

Therefore, the department concludes that there is reasonable assurance that VMMC will continue its relationships with ancillary and support services within the VMMC system, and approval of this project would not affect those relationships. This sub-criterion is met.

(3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs. Since 1994, the Department of Health's Office of Health Care Survey (OHCS), which surveys Hospitals and ASCs within Washington State, has completed eight compliance surveys of VMMC and twelve surveys of the five ASCs owned and operated by VMMC. Each of the surveys of VMMC revealed deficiencies, as did ten of the twelve ASC surveys. In each case, the deficiencies reported were typical of issues found at ASCs and did not indicate risk of immediate harm to patients. In each case, the findings were addressed satisfactorily in subsequent plans of correction. [source: compliance survey data provided by Office of Health Care Survey]

The current medical director for the facility is Douglas Merrill, MD. A review of Dr. Merrill's compliance history with Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [source: compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of the other operational health care facilities owned and/or operated by VMMC, and the compliance history of the medical director associated with the ASC, there is reasonable assurance that Virginia Mason Federal Way would continue to operate in conformance with applicable state and federal licensing and certification requirements. This sub-criterion is met.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

As noted earlier in this evaluation, the existing ASC is already operating as an exempt ASC. Approval of this project would open the facility to other physicians wishing access to it, in a planning area where a surplus of OR capacity currently exists and is expected to continue into the future. As a result, this project has the potential to exacerbate an existing situation where OR capacity is underutilized, potentially endangering the financial health and long-term existence of those other providers.

Based on the above information, the department concludes that there is not reasonable assurance that this project would promote continuity of care.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This sub-criterion is addressed in sub-section (3) above, and is met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has not met the applicable cost containment criteria in WAC 246-310-240.

- (1) <u>Superior alternatives</u>, in terms of cost, efficiency, or effectiveness, are not available or practicable. In response to this sub-criterion, the applicant stated that it had evaluated one alternative to the project described in this evaluation: do nothing. [source: Application, p24] The applicant decided to reject the "do nothing" option for three reasons:
 - 1. VMMC can undertake the project without any capital expenditure,
 - 2. VMMC has available capacity at the exempt ASC and VMMC's calculations indicated need in the planning area, and
 - 3. VMMC identified specific physician groups who are on its medical staff and unable to use the Federal Way facility due to its exempt status. [source: Application, p24]

The department concludes that the first reason listed above is not in dispute; however the second reason is discussed at length earlier in this evaluation. The department has concluded that there is a surplus of OR capacity in the planning area at present and in the near future. The department

cannot conclude that this reason is sufficient to justify this project. The third reason listed, allowing additional physician groups to use the VMMC Federal Way facility, is weakened by the failure of the applicant to demonstrate need for additional capacity. Because it has not demonstrated need for additional ORs and also has not demonstrated that these physicians are not able to serve their patients in existing facilities in the Southeast King planning area, the department cannot agree that this is a reason to adopt the proposed project.

Based on the information provided above, the department concludes that this project is not consistent with this sub-criterion.